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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. 3643 | |
|---|----------------|----------------------|-------------------------|-----------------------|--|
| 09/763,909 | 06/08/2001 | Rivka Dikstein | 13005-002001 | | |
| 7: | 590 12/03/2002 | | | | |
| Gregory P Einhorn Fish & Richardson Suite 500 4350 La Jolla Village Drive | | | EXAMINER | | |
| | | | DAVIS, MINH TAM B | | |
| | | | · | | |
| San Diego, CA | | | ART UNIT | PAPER NUMBER | |
| <i>3</i> , | | | 1642 | Λ 0 | |
| | | | DATE MAILED: 12/03/2002 | 12 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

| | Application No. | | Applicant(s) | | | | |
|---|---|--|---|----|--|--|--|
| | 09/763,909 | | DIKSTEIN ET AL. | • | | | |
| Office Action Summary | Examiner | | Art Unit | | | | |
| | MINH-TAM DAV | _ | 1642 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM | | | | | | | |
| THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, howe within the statutory mini will apply and will expire Soncesse the application to | ver, may a reply be time mum of thirty (30) days SIX (6) MONTHS from t become ABANDONED | ely filed will be considered timely. he mailing date of this cor 0 (35 U.S.C. § 133). | | | | |
| Status | | | | | | | |
| _ | | | | | | | |
| · | is action is non-fir | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | | |
| 4) ☐ Claim(s) 1-19 is/are pending in the application | | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) 1-19 are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | | | | | | |
| 9)☐ The specification is objected to by the Examiner | r. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11)☐ The proposed drawing correction filed on | is: a)∏ approve | d b)∐ disapprov | ved by the Examine | r. | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12)☐ The oath or declaration is objected to by the Exa | aminer. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a)☐ All b)☐ Some * c)☐ None of: | | | | | | | |
| Certified copies of the priority documents | 1. Certified copies of the priority documents have been received. | | | | | | |
| Certified copies of the priority documents | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachment(s) | - | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) 🗌 | | (PTO-413) Paper No(s atent Application (PTO | | | | |
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DETAILED ACTION

Applicant's election in paper No: 10 is acknowledged.

After review and reconsideration, the restriction of paper No:9 is vacated, and new restriction of claims 1-19 is required.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

- I. Claims 1-2, 6, 12-13, 15-16, 18-19, drawn to a DNA molecule encoding a fragment of the wild type TAF_{II} 105 polypeptide of SEQ ID NO:2 or a fragment of the wild type polynucleotide of SEQ ID NO:1, an expression vector comprising said DNA molecule, an antisense of SEQ ID NO:1.
- II. Claims 1-3, 6, 13, 15-16, 18-19, drawn to a DNA molecule encoding a mutant fragment of TAF_{II} 105 polypeptide consisting of amino acids 1 through 552 of SEQ ID NO:2, and an expression vector comprising said DNA molecule.
- III. Claims 1-2, 4-6, 13, 15-16, 18-19, drawn to a DNA molecule encoding a mutant fragment of TAF_{II} 105 polypeptide consisting of amino acids 1 through 452 of SEQ ID NO:2, and an expression vector comprising said DNA molecule.
- IV. Claims 1-2, 4-6, 13, 15-16, 18-19, drawn to a DNA molecule encoding a mutant fragment of TAF_{II} 105 polypeptide consisting of amino acids 1 through 359 of SEQ ID NO:2, and an expression vector comprising said DNA molecule.
- V. Claims 1-2, 4-6, 13, 15-16, 18-19, drawn to a DNA molecule encoding a mutant fragment of TAF_{II} 105 polypeptide consisting of amino acids 443 through 552 of SEQ ID NO:2, and an expression vector comprising said DNA molecule.

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VI. Claims 7-8, 13-14, 16, 18-19, drawn to a fragment of the wild type TAF_{II} 105 polypeptide.

VII. Claims 7-9, 11, 13-14, 16, 18-19, drawn to a mutant fragment of TAF_{II} 105 polypeptide, consisting of amino acids 1 through 552 of SEQ ID NO:2.

VIII. Claims 7-8, 10-11, 13-14, 16, 18-19, drawn to a mutant fragment of TAF $_{II}$ 105 polypeptide, consisting of amino acids 1 through 452 of SEQ ID NO:2.

- IX. Claims 7-8, 10-11, 13-14, 16, 18-19, drawn to a mutant fragment of TAF_{II} 105 polypeptide, consisting of amino acids 1 through 359 of SEQ ID NO:2.
- X. Claims 7-8, 10-11, 13-14, 16, 18-19, drawn to a mutant fragment of TAF_{II} 105 polypeptide, consisting of amino acids 443 through 552 of SEQ ID NO:2.
- XI. Claim 13, drawn to an inhibitor or antagonist of the wild type TAF_{II} 105 polypeptide of SEQ ID NO:2.

XII-XV. Claim 17, drawn to a method for promotion of apoptosis, comprising administering a DNA sequence encoding a mutant fragment of TAF_{II} 105 polypeptide, consisting of amino acids 1 through 552, 1-452, 1-359, 443-552 of SEQ ID NO:2. A method using each of the DNA sequence encoding a single mutant fragment of SEQ ID NO:2 constitutes a single invention, and not a species. Applicant is required to elect a single invention.

XVI. Claim 17, drawn to a method for promotion of apoptosis, comprising administering an antisense sequence of SEQ ID NO:1.

XVII-XXI. Claim 17, drawn to a method for promotion of apoptosis, comprising administering a fragment of the wild type TAF_{II} 105 polypeptide, or a mutant fragment of

TAF_{II} 105 polypeptide, consisting of amino acids 1 through 552, 1-452, 1-359, 443-552 of SEQ ID NO:2. A method using the wild type fragment or each of the mutant fragment of SEQ ID NO:2 constitutes a single invention, and not a species. Applicant is required to elect a single invention.

XXII. Claim 17, drawn to a method for promotion of apoptosis, comprising administering a DNA sequence encoding a fragment of the wild type TAF_{II} 105 polypeptide.

XXIII. Claim 17, drawn to a a method for promotion of apoptosis, comprising administering an inhibitor or antagonist of the wild type TAF_{II} 105 polypeptide of SEQ ID NO:2.

In addition, upon the election of any of groups I-X, further election of the following patentably distinct species of the claimed invention is required:

Autoimmune disease, inflammation, viral infection, bacterial infection.

The inventions listed as Groups I-XXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the

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category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as groups I-XXIII do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The technical feature of group I is a DNA molecule encoding a fragment of the wild type TAF_{II} 105 polypeptide. The wild type TAF_{II} 105 polypeptide however is known in the art, e.g. Dikstein et al, 1996, Cell, 87: 137-146, and US 5,710025, as disclosed in the specification on page 2, lines 12-15). Thus the technical feature of group I does not make a contribution over the prior art.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

July 26, 2002

SUSAŃ UNGAR, PH.D PRIMARY EXAMINER